

The Cited References

Grimberg et al. discloses a method for disinfecting a foodstuff-packaging material that includes contacting the packaging material with a liquid mixture of hydrogen peroxide that has been stabilized with foodstuff-compatible phosphonic acid. Grimberg et al. does not disclose using a concentration of 200 to 500 ppm of phosphonic acid as presently claimed. Instead, Grimberg et al. discloses using a concentration of less than 50 ppm, and even more preferably, a concentration of between 10 and 30 ppm.

Feasey et al. does not remedy the deficiency found in Grimberg et al. Feasey discloses a composition of hydrogen peroxide and a stabilizer (phosphonic acid). Feasey et al. teaches that the amount of stabilizer in the hydrogen peroxide composition is normally from 10 to 5000 ppm, irrespective of the hydrogen peroxide compound concentration, and that the actual amount of stabilizer varies according to the purpose of the composition (see column 4, lines 40-46). Feasey et al. then discloses, as examples, the following typical ranges in view of the corresponding uses: (a) 10 to 50 ppm in electronic grade solutions; (b) 50 to 1000 ppm in solutions intended for chemical synthesis; (c) about 1000 ppm in solutions intended for treating contact lenses; and (d) 1000 to 5000 ppm in solutions intended for the treatment of metals, such as metal pickling and polishing (see column 4, lines 46-58).

Non-Obviousness of Present Invention

The Office Action asserts that Example 5 of Feasey et al. demonstrates the most effective concentration of stabilizer in the solution. This statement is *not* correct. The range taught in Example 5 relates to a *specific use*, namely the stabilization of *diluted* hydrogen peroxide solutions (3%w/w) suitable for use in *sterilizing contact lenses* (see column 7, lines 13-17). The range taught in this specific example *cannot be used* as the general teaching of Feasey et al. The general teaching of Feasey et al. is instead 10 to 5000 ppm. The Office Action even acknowledges that the specific examples disclosed in Feasey are for

“illustrative purposes only” and should not be used to limit the applications of the reference (see page 6 of Office Action). This hindsight reconstruction of pulling the concentration range from one specific example and calling it the “most effective concentration” disclosed in the reference is doing exactly what the Office Action describes as impermissibly limiting the applications of the reference.

The general teaching of Feasey is not one particular range that is the “most effective range”, but instead gives various different ranges that are most effective for the particular intended use. The overall concentration range taught in the reference is, in fact, from 10 to 5000 ppm. Therefore, if one of ordinary skill in the art was motivated to modify the range disclosed in Grimberg (10 to 30 ppm) by using the teaching of Feasey (10 to 5000 ppm), they would not arrive at the presently claimed invention. The range taught in Feasey is over 150 times broader than the range taught in Grimberg, and one skilled in the art would not be directed to the narrow claimed range of 200 to 500 ppm. Accordingly, the combination of Grimberg and Feasey does not render the presently claimed invention obvious.

Assuming *arguendo* that a person skilled in the art was motivated to modify the concentration range as taught in Grimberg by looking at Feasey, that skilled person would look to all of the examples provided in the reference as a starting point to determine the concentration of stabilizer to use in the solution. Based on all of examples, a person skilled in the art would look to the methods taught by Feasey that most closely resemble the problem needing to be solved. The following chart highlights the method of the present invention, compared to the method the Office Action looks to for guidance, as well as to the method in the reference that a person skilled in the art would actually look to for guidance based on the similarities in the methods:

	Food packaging sterilization	Contact lenses sterilization	Metal pickling
H ₂ O ₂ concentration	35 %	3 %	35 %
H ₂ O ₂ purity	Progressively contaminated with packaging material residues (plastics, metals)	High purity	Progressively contaminated with metals
Type of treatment	Continuous , by dipping in baths	Batch	Continuous , by dipping in pickling baths
Treatment temperature	Heated to 70-85°C	Room temperature	Heated to 45-70°C
Time to perform the treatment	Several seconds	5-15 minutes	Short time , 2-4 minutes
Total treatment (use) time for the H ₂ O ₂ solution	Several hours	5-15 minutes	Long time

It is clear from the above chart, that the method relating to metal pickling or polishing is much more similar to the presently claimed invention than the method of sterilizing contact lenses. Therefore, a person of ordinary skill in the art that is trying to improve the method of sterilizing foodstuff-packaging would look to the examples in Feasey et al. relating to the metal pickling or polishing and *not* the examples relating to sterilizing contact lenses. One skilled in the art, looking to modify the teaching of Grimberg et al., would start by testing concentrations as described for use in metal pickling and polishing by Feasey et al. (i.e. phosphonic acid concentration of at least 1000 ppm, see column 4, lines 54-58), and would not ever reach the range of the presently claimed invention (200 to 500 ppm).

Accordingly, the combination of Grimberg et al. and Feasey et al., considered together with the knowledge and skill of a person of ordinary skill in

the art, fails to disclose or suggest all of the features of the presently claimed invention or to make out a proper *prima facie* case of obviousness.

Evidence of Unexpected Results

Moreover, even if a *prima facie* case of obviousness had been made out by the references, any *prima facie* case would be effectively rebutted by the evidence of record which shows that the results obtained using the presently claimed method were unexpected and surprising. The Declaration under 37 C.F.R. § 1.132, signed by both inventors, and submitted February 18, 2009, clearly shows that persons skilled in the art were surprised by the results obtained when using the presently claimed concentration of phosphonic acid. The assertion in the Office Action mailed March 25, 2009 that the declaration constitutes mere arguments and not facts shows that the Office has not given proper weight to this Declaration of qualified experts skilled in the art. The Declaration shows that ***experts in the art*** were surprised by the stability of the hydrogen peroxide when using 200 to 500 ppm of phosphonic acid, and when using elevated temperatures. The statements made by these experts in the art must be given weight, even without implicit data corroborating the statements (as argued in the Office Action mailed March 25, 2009), because these statements show that the results were unexpected given the state of the art at the time of the invention. The applicants request that the Office fully consider the Declaration as evidence of the unexpected and superior results achieved when using the claimed method.

The evidence of unexpected and superior results in the present invention effectively rebuts any *prima facie* case of obviousness allegedly made out by the references. Therefore, for the reasons discussed above, withdrawal of the obviousness rejection over Grimberg et al. and Feasey et al. is respectfully requested.

Second Obviousness Rejection

The rejection of claim 8 under 35 U.S.C. § 103(a) over Grimberg et al. and Feasey et al. in view of Voegle et al., US 4,104,024, is also respectfully traversed.

Voegle et al. is cited to show the controlling temperature of the hydrogen peroxide bath. As the Office Action points out, Voegle et al. teaches that it is known to heat hydrogen peroxide baths to a temperature of 90°C, but that maintaining such a high temperature is complex and expensive (see page 5 of Office Action). The Office Action then asserts that it would have been obvious to one skilled in the art to further modify the teaching of Grimberg and Feasey to heat the hydrogen bath to a temperature below 90°C as taught by Voegle since this temperature range destroys all bacteria spores (see page 5 of Office Action). Applicants respectfully disagree with this assertion.

Indeed, Voegle et al. discloses that it is known in the art to sterilize packaging materials using a 30% solution of hydrogen peroxide at a temperature around 90°C. But Voegle et al. also teaches that this process, which allows the destruction of all bacterial spores, is complex, dangerous and expensive. Because of the risks involved in the method using hydrogen peroxide, Voegle teaches a method with an active-chlorine solution as the sterilizing solution, not hydrogen peroxide. This new method disclosed by Voegle allows for sterilization with this active-chlorine solution at lower temperatures and without the need for high concentrations of hydrogen peroxide solutions (see column 1, lines 27-50). The reference teaches the use of hydrogen peroxide as a deactivating agent to the remaining active-chlorine *after* the sterilization has been completed (see column 1, lines 35-40). A person skilled in the art, following the teaching of Voegle et al., would be instructed away from the use of hydrogen peroxide as a sterilizing agent.

Accordingly, a person looking to modify the teaching of Grimberg et al and Feasey et al. would not look to Voegle et al. for ways to modify the method of

using hydrogen peroxide to sterilize packaging materials because Vogele et al. does not use hydrogen peroxide to sterilize materials, and therefore, the combination of the references fail to render the present invention obvious.

Reconsideration and withdrawal of the obviousness rejections are accordingly, respectfully requested.

Conclusion

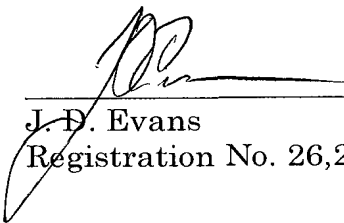
For the foregoing reasons, the application is respectfully requested to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323, Docket No. 101771.53337US.

Respectfully submitted,

June 9, 2010



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